IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 1203
THIS DOCUMENT RELATES TO:	:	
SHEILA BROWN, et al.	:	CIVIL ACTION NO. 99-20593
v.	:	
AMERICAN HOME PRODUCTS CORPORATION	:	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9477

Bartle, J. September 30, 2016

Tammy Radandt ("Ms. Radandt" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD").

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October 2013, claimant submitted a supplemental Green Form to the Trust signed by her attesting physician, Martin G. Keane, M.D. ("Dr. Keane").[3] Based on an echocardiogram dated February 3, 2002, Dr. Keane attested in Part II of Ms. Radandt's Green Form that claimant had severe mitral regurgitation, surgery to repair or replace the aortic and/or

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See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. In April, 2014, claimant submitted an amended Part II of the Green Form. This submission is the basis for the present claim.

mitral valve(s) following the use of Pondimin® and/or Redux™, New York Heart Association Functional Class II symptoms,[4] and a left ventricular ejection fraction < 40% at any time six months or later after valvular repair or replacement surgery.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level IV[6] benefits in the amount of $966,820.45.[7]

Dr. Keane also attested that Ms. Radandt did not suffer from mitral annual calcification or a rheumatic mitral

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4. Although Dr. Keane initially attested that Ms. Radandt suffered from New York Heart Association Functional Class IV symptoms, he subsequently stated—and claimant conceded — that she suffered from New York Heart Association Functional Class II symptoms.

5. Dr. Keane also attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation and an abnormal left ventricular dimension. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she qualifies for payment at Matrix Level III, has New York Heart Association Functional Class I or Class II symptoms, underwent surgery to repair or replace the aortic and/or mitral valve(s), and had a left ventricular ejection fraction of less than 40% six months or later after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(4)(c). The Trust does not dispute that Ms. Radandt qualifies for payment at Matrix Level III, has New York Heart Association Functional Class II symptoms, and underwent mitral valve surgery.

7. Ms. Radandt previously received Seventh Amendment Category One Benefits in the amount of $180,170.55. According to the Trust, if entitled to Matrix A-1, Level IV benefits, claimant would be entitled to Matrix Benefits in the amount of $1,146,991. The amount at issue, therefore, is the difference between the Category One Benefits already paid and the amount of Matrix A-1, Level IV benefits. See id. § IV.C.3.

valve. Under the Settlement Agreement, the presence of either of these conditions requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See id. §§ IV.B.2.d.(2)(c)ii)d), IV.B.2.d.(2)(c)ii)e).[8]

In May 2014, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., F.A.S.E. ("Dr. Irani"), one of its auditing cardiologists. Dr. Irani accepted the attesting physician's conclusion that Ms. Radandt suffered from the conditions necessary for Level IV Matrix Benefits. However, he also found that there was no reasonable medical basis for Dr. Keane's finding that claimant did not have mitral annual calcification. Pursuant to Court Approved Procedure ("CAP") No. 11, the Consensus Expert Panel[9] subsequently reviewed Ms. Radandt's claim and determined that the claim should be re-audited because the "[g]roup finds [a reasonable medical basis] for [the] attesting physician's finding of no mitral

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8. If Ms. Radandt's supplemental claim Matrix Benefits is payable only on Matrix B-1, she will not receive any additional payment because the amount to which she would be entitled is less than the amount of Category One Benefits she previously received pursuant to the Seventh Amendment.

9. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2005). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

annular calcification." In October 2014, the Trust informed Ms. Radandt that it had accepted the Consensus Expert Panel's recommendation that her claim be re-audited.

In June 2015, the Trust forwarded the claim for review by another auditing cardiologist, Zuyue Wang, M.D., F.A.C.C., F.A.S.E. ("Dr. Wang"). In audit, Dr. Wang concluded that there was no reasonable medical basis for finding that claimant had an ejection fraction of less than 40% six months or later after her mitral valve surgery. Dr. Wang explained:

> The claimant did not have a 6 month [echocardiogram]; her [echocardiogram] on 3/26/12 (9 months post-op) showed [an] [ejection fraction] of 65%.

Dr. Wang also determined that there was no reasonable medical basis for Dr. Keane's finding that claimant did not have a rheumatic mitral valve. Dr. Wang observed:

> There are many [echocardiographic] features of rheumatic mitral valve disease: 1) leaflets thickening especially at the tip, with diastolic doming[,] 2) chordal thickening, 3) restricted motion of posterior mitral leaflet, 4) commissural fusion, 5) moderate to severe mitral stenosis with mitral valve area of 1.6cm2.

Based on Dr. Wang's findings, the Trust issued a post-audit determination that Ms. Radandt was not entitled to supplemental Matrix Benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant

contested these adverse determinations.[10] In contest, Ms. Radandt argued that there was a reasonable medical basis for finding that she was entitled to Matrix A, Level IV benefits. In addition, claimant stated that "[a] mere difference of opinion is not sufficient to deny this claim." She also argued that the auditing cardiologist substituted her subjective opinion for the opinion of the attesting physician.

With respect to whether her ejection fraction was less than 40% six months or later after her mitral valve surgery, claimant argued that "while the Auditing Cardiologist and [Jay N. Schapira, M.D., F.A.C.C., F.A.C.P., F.C.C.P., F.A.H.A. ("Dr. Schapira")] agree that the March 2012 echocardiogram shows a [left ventricular ejection fraction] over 40%, the March 2012 echocardiogram report indicated a [left ventricular ejection fraction] of 40% and Ms. Radandt had a [left ventricular ejection fraction] of 20-25% over five and ½ months after her surgery."

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10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Radandt's claim.

With respect to whether she had a rheumatic mitral valve, claimant contended that "it is very difficult to establish that the Attesting Physician's findings and answer . . . [is] devoid of any reasonable medical basis" because there is not a diagnosis of rheumatic mitral valve in any of her medical records. In addition, Ms. Radandt submitted a number of medical records and a letter from Dr. Schapira, wherein he stated:

> I do not find M-mode and/or 2D echocardiographic evidence of rheumatic valvular heart disease. I carefully reviewed the VHS tape dated 2-23-02 and in my opinion this showed no evidence of rheumatic disease in the mitral valve: no fusion, no mitral stenosis and no doming of the mitral leaflets was present. . . .
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> Subsequent transthoracic echocardiographic studies, including September 24, 2009 and August 26, 2010, also revealed no sign of rheumatic valve disease. There was no gradient on spectral Doppler across the mitral valve in either study and therefore no mitral stenosis. Clearly, these studies do not show evidence of a rheumatic valve disease and I disagree with the conclusion of the auditor.
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> The pathological diagnosis of the mitral valve at the time of Tammy Radant's [sic] mitral valve replacement surgery was that of "fibromyxoid degeneration," again not consistent with rheumatic disease.
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> . . . .
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> My opinion is that to a reasonable degree of medical certainty, Tammy Radant's [sic] mitral valve disease was due to her diet drug exposure.

Although not required to do so, the Trust forwarded the claim for another review by the auditing cardiologist. Dr. Wang submitted a declaration in which she again concluded that Ms. Radandt did not have an ejection fraction of less than 40% six months or later after her mitral valve surgery. Specifically, Dr. Wang stated:

> Claimant underwent mitral valve surgery on June 1, 2011. The March 26, 2012 echocardiogram, which is the sole echocardiogram performed six months or more after Claimant's surgery, shows an ejection fraction of 60-65%. Even Dr. Schapira found an ejection fraction of greater than 50% at the time of the March 2012 study. I do not agree with the assertion at Contest that, because the November 11, 2011 report indicates an ejection fraction of 20-25%, Claimant's ejection fraction must have been less than 40% six months or more after surgery. It is likely that Claimant's ejection fraction improved in the weeks preceding the six month cut off. There are no medical records documenting an ejection fraction below 40% at any time six months or later after mitral valve surgery.

Dr. Wang also confirmed her finding that there was no reasonable medical basis for Dr. Keane's representation that Ms. Radandt did not have echocardiographic evidence of a rheumatic mitral valve. She explained:

> I observed thickening at the tip of the mitral leaflets with diastolic doming, mild fusion of chordae and commissure which resulted in mild mitral stenosis with mitral valve area of 2.2cm2 by pressure half time method. (A normal mitral valve area is 4-6cm2). Claimant had mild mitral stenosis

> and severe mitral regurgitation, which is consistent with rheumatic heart valves rather than Diet Drug valvulopathy. The pathology report does not rule out rheumatic valve disease.

The Trust then issued a final post-audit determination that Ms. Radandt was not entitled to supplemental Matrix Benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Radandt's claim should be paid. On October 5, 2015, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9439 (Oct. 5, 2015).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 5, 2016. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[11] to review claims after the Trust

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge - helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as (continued...)

and claimant have had the opportunity to develop the show cause record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C. ("Dr. Vigilante"), to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's findings that Ms. Radandt (1) had an ejection fraction less than 40% at any time six months or later after valvular repair or replacement surgery and (2) did not have echocardiographic evidence of a rheumatic mitral valve. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order

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this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Radandt reasserts the arguments she raised in contest. She points to Dr. Keane's representation that Ms. Radandt had an ejection fraction of less than 40% six months or later after her mitral valve surgery. She argues that there is a reasonable medical basis for the finding. Even though claimant did not have an echocardiogram performed exactly six months after her mitral valve surgery, she asserts that "it is unlikely that [her] [left ventricular ejection fraction] would have climbed 16-21% in a matter of eleven days."

With respect to Dr. Keane's representation that Ms. Radandt did not have a rheumatic mitral valve, claimant maintains that it has a reasonable medical basis since neither the surgeon nor the cardiologist diagnosed Ms.Radandt with rheumatic mitral valve and both of them attributed her condition to Diet Drug use.

In addition, claimant asserts that she has never had rheumatic fever and that chordal thickening and shortening and thickening of leaflets are seen in patients with drug-induced valvular heart disease.

Finally, claimant contends that "[t]he clinical diagnoses and medical opinions of a Claimant's treating board-

significant weight when determining if a Claimant has met his/her burden."

In response, the Trust argues that Dr. Wang, as well as claimant's own expert, Dr. Schapira, reviewed the only echocardiogram performed more than six months after claimant's mitral valve surgery and determined that it demonstrated an ejection fraction that was greater than 40%. Further, the Trust asserts that the absence of any reference to rheumatic mitral valve in the pathology report and the absence of a diagnosis of rheumatic fever are insufficient to overcome the echocardiographic evidence of rheumatic mitral valve. Finally, the Trust contends that claimant's treating physicians are not entitled to any deference in the audit process.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant suffered from an ejection fraction less than 40% six months or later after valvular repair or replacement surgery. Specifically, Dr. Vigilante stated, in pertinent part:

> I reviewed the Claimant's echocardiogram of October 26, 2011. All 65 loops/images were evaluated. This was an excellent quality study. There was significant dilation of the left ventricle with severe diffuse decrease in contractility and an estimated ejection fraction of 20%. . . .

> I reviewed the CD of the Claimant's echocardiogram dated March 26, 2012. All 67 loops/images were reviewed. This was a good quality study with the usual echocardiographic views obtained. . . . I then calculated the ejection fraction by Simpson's Method. I determined that the left ventricular ejection fraction was 62%. . . . .
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> . . . .
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> [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question K. That is, the only echocardiogram performed 6 months or later after mitral valve replacement surgery demonstrated a left ventricular ejection fraction of 62%. This ejection fraction was not even close to 40%. It is possible for an ejection fraction to substantially increase within one month for a number of reasons including recovery after cardiac surgery, improvement in hemodynamics, and appropriate medical treatment. An echocardiographer could not reasonably conclude that an ejection fraction of less than 40% was present on an echocardiogram performed 6 months or later after mitral valve replacement surgery.

Dr. Vigilante also determined that there was no reasonable medical basis for the attesting physician's finding that Ms. Radandt did not have a rheumatic mitral valve. In support of this conclusion, Dr. Vigilante explained:

> I reviewed the DVD and tapes of the Claimant's Echocardiogram of Attestation. This study was dated February 3, 2002. All copies demonstrated the same study. . . . All 158 loops were reviewed. This was a below quality study with excessive color gain. However, there was adequate evaluation of the mitral apparatus. This study demonstrated excellent views of the

mitral valve apparatus particularly in the view. There was obvious doming of both anterior and posterior mitral valve leaflets as well as thickening of the tips of the leaflets. There was commissural fusion. This was a classic rheumatic mitral valve. . . .

I reviewed the Claimant's echocardiogram of July 17, 2003. This was a below average quality study. However, there was thickening of both mitral leaflets particularly the tips of both leaflets. In addition, there was classic doming and commissural fusion . . . .

I also reviewed the Claimant's echocardiogram of April 21, 2004. This was a better quality study than the previous echocardiogram. This study demonstrated significant thickening of the mitral leaflets with obvious doming and commissural fusion. Significant mitral stenosis was not present. This was a classic rheumatic mitral valve. . . .

I reviewed the Claimant's transesophageal echocardiogram of August 12, 2008. This study demonstrated classic doming of the mitral leaflets and commissural fusion. The mitral leaflets were thickened. There was severe mitral regurgitation. There was no significant mitral stenosis. This was a classic rheumatic mitral valve. . . .

I reviewed the Claimant's echocardiogram dated September 24, 2009. I reviewed all 79 loops/images. This was a reasonable quality study with the usual echocardiographic views obtained. There were significant abnormalities of the mitral valve. There was moderate thickening of the mitral valve particularly tips of both leaflets with definite doming and commissural fusion classic for rheumatic mitral valvular disease. This was best seen in loops 1, 27, 57, and 61. . . .

I reviewed the Claimant's echocardiogram of August 26, 2010. All 71 loops/images were reviewed. This study was of adequate quality. There were marked abnormalities of the mitral apparatus. There is significant thickening of the tips and body of both mitral leaflets. There is obvious doming and commissural fusion. This is best seen in loop 26. . . . Thickening of the chordal structures consistent with rheumatic valvular disease is also obvious on the parasternal long-axis view best visualized in loops 2 and 4. . . .

I reviewed the echocardiogram of October 1, 2010. This was a relatively limited study with only 17 loops/images. However, severe abnormalities of the mitral apparatus could be seen. There was significant thickening of both mitral leaflets with doming and commissural fusion. This was best seen in loops 1, 5, and 6. Significant thickening of the chordal structure was seen in loop 10. These findings are classic for rheumatic mitral valvular disease. . . .

. . . .

I reviewed the Claimant's transesophageal [echocardiogram] of June 11, 2011. I reviewed all 14 loops. This was the intra-operative study. The first loop showed obvious doming of both mitral leaflets as well as thickening of the tips of the leaflets. There was obvious commissural fusion. Loop 3 demonstrated definite thickening of the chordae tendineae as well as severe mitral regurgitation. This study was classic for rheumatic mitral valvular disease. . . .

. . . .

[T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question D.10. That is, all of the Claimant's pre-operative echocardiograms

> demonstrate obvious evidence of rheumatic mitral valves with doming of the anterior leaflet and commissural fusion with comments as above. An echocardiographer could not reasonably conclude that there was no echocardiographic evidence of rheumatic mitral valves on these studies. In addition, a Board-Certified pathologist has not determined that there was no evidence of rheumatic valve disease on pathological examination of the mitral valve tissue.

Claimant submitted a response to the Technical Advisor report. With respect to the level of her ejection fraction, claimant states that she "does not dispute the fact that [a] [left ventricular ejection fraction] may substantially increase in a one-month period of time." She argues, however, that this is not dispositive because "Dr. Keane's medical opinion was that, more likely than not, Ms. Radandt's [left ventricular ejection fraction] did not jump from 20% on October 26, 2011, to over 40% by November 10, 2011." As to whether she had a rheumatic mitral valve, claimant suggests that we should ignore Dr. Vigilante's opinion because he says she had a "classic rheumatic valve," a "broad-brush" term that is not contemplated by the Settlement Agreement or evaluable by claimant. She also concedes that her treating physicians noted a "thickened" mitral valve in her history, but she simply argues that it is "consistent with Fen-Phen valvulopathy" and that "an [echocardiogram] image is not, by itself, sufficient to diagnose the presence of rheumatic valve disease."

After reviewing the entire Show Cause Record, we find that claimant has failed to establish a reasonable medical basis for her claim. First, claimant has failed to meet her burden with respect to establishing a reasonable medical basis for the attesting physician's Green Form representation that Ms. Radandt had an ejection fraction of less than 40% six months or later after valvular repair or replacement surgery. As an initial matter, we previously have rejected the argument that a claimant may rely solely on records of medical procedures performed within the six month period after her mitral valve surgery to establish an ejection fraction six months or more after surgery. See, e.g., Mem. in Supp. of Separate PTO No. 8976, at 8 n.11 (Nov. 28, 2012).

Moreover, claimant's reliance on the only echocardiogram conducted six months or later after her mitral valve surgery for evidence that she had an ejection fraction of less than 40% months earlier is misplaced. Although Ms. Radandt points out that the reviewing cardiologist estimated claimant's ejection fraction to be 40% based on the March 26, 2012 echocardiogram, her own expert, Dr. Schapira, noted that this echocardiogram demonstrated an ejection fraction of greater than 50%. In addition, Dr. Wang and Dr. Vigilante reviewed the echocardiogram and determined that it was actually in the range

of 60% to 65%.[12] Claimant does not challenge these determinations that her echocardiogram demonstrates an ejection fraction much higher than 40%.

In addition, Dr. Vigilante noted – and claimant does not dispute – that "[i]t is possible for an ejection fraction to substantially increase within one month for a number of reasons including recovery after cardiac surgery, improvement in hemodynamics, and appropriate medical treatment." We do not accept claimant's argument that this possibility "is not controlling" because Dr. Keane's opinion was that it was "more likely than not" that Ms. Radandt's ejection fraction "did not jump from 20% on October 26, 2011, to over 40% by November 10, 2011." Claimant's ejection fraction was well over 40% on the only echocardiogram that was performed more than six months following her mitral valve surgery. Under the circumstances of this case, claimant has failed to establish a reasonable medical basis for her attesting physician's finding that she had an ejection fraction of less than 40% six months or later after her mitral valve surgery.

Second, claimant has failed to meet her burden with respect to establishing a reasonable medical basis for the

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12. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted her opinion for the opinion of the attesting physician.

attesting physician's Green Form representation that Ms. Radandt did not have a rheumatic mitral valve. The Settlement Agreement provides that a claimant will receive reduced Matrix Benefits when certain enumerated medical conditions are present, including a rheumatic mitral valve defined as follows:

> M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease.

Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Here, the auditing cardiologist determined that claimant's echocardiogram revealed "many [echocardiographic] features of rheumatic mitral valve disease: 1) leaflets thickening especially at the tip, with diastolic doming[,] 2) chordal thickening, 3) restricted motion of posterior mitral leaflet, 4) commissural fusion, 5) moderate to severe mitral stenosis with mitral valve area of 1.6cm2." The Technical Advisor also reviewed each of claimant's echocardiograms and concluded that almost all of them demonstrated a classic rheumatic mitral valve. He explained, for example, with respect to claimant's February 3, 2002 echocardiogram, that "[t]here was obvious doming of both anterior and posterior mitral valve leaflets as well as thickening of the tips of the leaflets" and that "[t]here was

commissural fusion." Dr. Vigilante made similar findings with respect to claimant's echocardiograms of July 17, 2003, April 21, 2004, April 12, 2008, September 24, 2009, August 26, 2010, October 1, 2010, and June 11, 2011. Dr. Vigilante even noted specific frames in many of the studies that demonstrated the doming, thickening, and commissural fusion that he observed.[13]

Ms. Radandt did not adequately refute these findings. Although she submitted a letter from Dr. Schapira, he only stated that he reviewed claimant's echocardiograms of February 23, 2002, September 24, 2009, and August 26, 2010, and that "these studies do not show evidence of a rheumatic valve disease and I disagree with the conclusion of the auditor."

Claimant also does not dispute that there was evidence of mitral valve and chordal thickening in her echocardiograms. Instead, she argues that her "mitral valve disease was due to her diet drug exposure" rather than a rheumatic mitral valve. This argument is irrelevant. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimants are required to show that they meet, or in the case of the presence

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13. We therefore reject claimant's argument that Dr. Vigilante's use of the phrase "classic rheumatic mitral valve" is a "broad-brush" term that claimant cannot "test or evaluate." To the contrary, Dr. Vigilante identified at length the very evidence of rheumatic mitral valve referred to in the Settlement Agreement that he observed on Ms. Radandt's echocardiograms.

of reduction factors, do not meet, the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred. . . .

Mem. in Supp. of Separate PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

> . . . [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse is also true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. The Settlement Agreement unequivocally requires a mitral valve claim to be reduced to Matrix B if claimant's echocardiogram reveals evidence of a rheumatic mitral valve[14] and

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14. For this reason as well, we disagree with claimant that the standard to be applied is whether one can diagnose rheumatic mitral valve from an echocardiogram. The Settlement Agreement plainly requires that a claim but be reduced if there is "evidence" of a rheumatic mitral valve on a claimant's

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a Board-Certified Pathologist has not provided a contrary determination after examination of the mitral valve tissue. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that the cause of her mitral valve condition was the ingestion of Diet Drugs is irrelevant to the issue before the court.

Claimant's argument that she satisfied the requirements of the Settlement Agreement because her pathologist examined her mitral valve tissue and did not make a finding of rheumatic mitral valve is erroneous. We previously have held, "Only upon a specific finding by a Board-Certified Pathologist that the mitral valve tissue does not reveal evidence of rheumatic valve disease may a claimant avoid application of the reduction factor at issue." Mem. in Supp. of Separate PTO No. 9070 at 9 (May 21, 2013). As a Board-Certified Pathologist has not made a specific finding that Ms. Radandt's mitral valve was not rheumatic, the Settlement Agreement requires that her claim be reduced to Matrix B-1.

Finally, claimant's attempted reliance on her representation that she was never diagnosed with rheumatic fever

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echocardiogram, "except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease." Settlement Agreement § IV.B.2.d.(2)(c)ii)e).

also is misplaced. Nothing in the Settlement Agreement provides that evidence of the reduction factor of a rheumatic mitral valve on a claimant's echocardiogram may be disregarded based on an assertion that the claimant never was diagnosed or treated for rheumatic fever. We previously have held that a claimant cannot meet his or her burden of proving the absence of rheumatic mitral valve by reference to statements from a parent and family physician to the effect that claimant never had rheumatic fever. See, e.g., Mem. in Supp. of Separate PTO No. 7466, at 10 (Oct. 10, 2007). As stated in the Settlement Agreement, the only means by which a claimant may rebut echocardiographic evidence of rheumatic valve disease is the specific determination of a Board-Certified Pathologist. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Claimant has not provided such a determination in this case.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for her claim for Matrix A-1, Level IV benefits. Therefore, we will affirm the Trust's denial of Ms. Radandt's claim for supplemental Matrix Benefits.